

DEPARTMENT OF COMMERCE
Patent and Trademark Office
[Docket No. 950706172-5172-01]
Utility Examination Guidelines

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The Patent and Trademark Office (PTO) is publishing the final version of guidelines to be used by Office personnel in their review of patent applications for compliance with the utility requirement. Because these guidelines govern internal practices, they are exempt from notice and comment and delayed effective date rulemaking requirements under 5 U.S.C. § 553(b)(A).

EFFECTIVE DATE: [Insert date of publication in Federal Register]

FOR FURTHER INFORMATION CONTACT: Jeff Kushan by telephone at (703) 305 -9300, by fax at (703) 305 -8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION

I. Discussion of Public Comments

Forty-four comments were received by the Office in response to the request for public comment on the proposed version of utility guide lines published on January 3, 1995 (60 FR 97). All comments have been carefully considered. A number of changes have been made to the examining guidelines and the legal analysis supporting the guidelines in response to the comments received.

Many of the individuals responding to the request for public comments suggested that the Office address the relationship between the requirements of 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 101. The Office has amended the guidelines to provide a clarification consistent with these requests. The guidelines now specify that any rejection based on a "lack of utility" under § 101 should be accompanied by a rejection based upon § 112, first paragraph. The guidelines also specify that the procedures for imposition and review of rejections based on lack of utility under § 101 shall be followed with respect to the § 112 rejection that accompanies the § 101 rejection.

A suggestion was made that the guidelines should be modified to provide that an application shall be presumed to be compliant with § 112, first paragraph, if there is no proper basis for imposing a § 101 rejection. This suggestion has not been followed. Instead, the guidelines specify that § 112, first paragraph, deficiencies other than those that are based on a lack of utility be addressed separately from those based on lack of utility for the invention.

Several individuals suggested that the guidelines address how § 101 compliance will be reviewed for products that are either intermediates or whose ultimate function or use is unknown. The Office has amended the guidelines to clarify how it will interpret the specific utility requirement of § 101.

Some individuals suggested that the guidelines be amended to preclude Examiners from requiring that an applicant delete references made in the specification to the utility

of an invention which are not necessary to support an asserted utility of the claimed invention. The guidelines have been amended consistent with this suggestion.

One individual suggested that the legal analysis be amended to emphasize that any combination of evidence from in vitro or in vivo testing can be sufficient to establish the credibility of an asserted utility. The legal analysis has been amended consistent with this recommendation.

A number of individuals questioned the legal status of the guidelines, particularly with respect to situations where an applicant believes that a particular Examiner has failed to follow the requirements of the guidelines in imposing a rejection under § 101. The guidelines and the legal analysis supporting the guidelines govern the internal operations of the Patent and Trademark Office. They are not intended to, nor do they have the force and effect of law. As such they are not substantive rules creating or altering the rights or obligations of any party. Rather, the guidelines define the procedures to be followed by Office personnel in their review of applications for § 101 compliance. The legal analysis supporting the guidelines articulates the basis for the procedures established in the guidelines. Thus, an applicant who believes his or her application has been rejected in a manner that is inconsistent with the guidelines should respond substantively to the grounds of the rejection. "Non-compliance" with the guidelines will not be a petitionable or appealable action.

Some individuals suggested that the guidelines and legal analysis be amended to specify that the Office will reject an application for lacking utility only in those situations where the asserted utility is "incredible." This suggestion has not been adopted. The Office has carefully reviewed the legal precedent governing application of the utility requirement. Based on that review, the Office has chosen to focus the review for compliance with § 101 and § 112, first paragraph, on the "credibility" of an asserted utility.

Some individuals suggested that the guidelines be amended to address how a generic claim that covers many discrete species will be assessed with regard to the useful invention requirements of § 101 and 112 when one or more, but not all, species within the genus do not have a credible utility. The guidelines have been amended to

clarify how the Office will address applications in which genus claims are presented that encompass species for which an asserted utility is not credible. The legal analysis makes clear that any rejection of any claimed subject matter based on lack of utility must adhere to the standards imposed by these guidelines. This is true regardless of whether the claim defines only a single embodiment of the invention, multiple discrete embodiments of the invention, or a genus encompassing many embodiments of the invention. As cast in the legal analysis and the guidelines, the focus of examination is the invention as it has been defined in the claims.

Some individuals questioned whether the guidelines and the legal analysis govern actions taken by Examining Groups other than Group 1800 or the Board of Patent Appeals and Interferences. The guidelines apply to all Office personnel, and to the review of all applications, regardless of field of technology.

In addition to the changes made in response to comments from the public, the Office has amended the guidelines to clarify the procedure to be followed when an applicant has failed to identify a specific utility for an invention. The guidelines now provide that where an applicant has made no assertion as to why an invention is believed useful, and it is not immediately apparent why the invention would be considered useful, the Office will reject the application as failing to identify any specific utility for the invention. The legal analysis has also been amended to address evaluation of this question.

II. Guidelines for Examination of Applications for Compliance with the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any application for compliance with the utility requirements of 35 U.S.C. § 101 and _ 112. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and

human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement.

The guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The guidelines and the legal analysis do not alter the substantive requirements of 35 U.S.C. § 101 and § 112, nor are they designed to obviate review of applications for compliance with this statutory requirement.

B. Examination Guidelines for the Utility Requirement

Office personnel shall adhere to the following procedures when reviewing applications for compliance with the useful invention (utility) requirement of 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

1. Read the specification, including the claims, to

- a) determine what the applicant has invented, noting any specific embodiments of the invention;
- b) ensure that the claims define statutory subject matter (e.g., a process, machine, manufacture, or composition of matter);
- c) note if applicant has disclosed any specific reasons why the invention is believed to be useful.

2. Review the specification and claims to determine if the applicant has asserted any credible utility for the claimed invention

- a) If the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., a "specific utility") and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view

of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicants assertions. An applicant must provide only one credible assertion of specific utility for any claimed invention to satisfy the utility requirement.

- b) If the invention has a well -established utility, regardless of any assertion made by the applicant, do not impose a rejection based on lack of utility. An invention has a well -established utility if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties of a product or obvious application of a process).
- c) If the applicant has not asserted any specific utility for the claimed invention and it does not have a -well-established utility, impose a rejection under _§ 101, emphasizing that the applicant has not disclosed a specific utility for the invention. Also impose a separate rejection under _§ 112, first paragraph, on the basis that the applicant has not shown how to use the invention due to lack of disclosure of a specific utility. The _§ 101 and § 112, rejections should shift the burden to the applicant to:
 - explicitly identify a specific utility for the claimed invention, and
 - indicate where support for the asserted utility can be found in the specification.

Review the subsequently asserted utility by the applicant using the standard outlined in paragraph (2)(a) above, and ensure that it is fully supported by the original disclosure.

3. If no assertion of specific utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a well -established utility reject the claim(s) under § 101 on the grounds he

claims invention as claimed lacks utility. Also reject the claims under § 112 first paragraph on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection and should be set out as a rejection distinct from any other rejection under § 112, first paragraph, not based on lack of utility for the claimed invention.

To be considered appropriate by the Office, any rejection based on lack of utility must include the following elements:

a) A prima facie showing that the claimed invention has no utility

A prima facie showing of no utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific utility asserted by the applicant for the claimed invention. A prima facie showing must contain the following elements:

- i) a well-reasoned statement that clearly sets forth the reasoning used in concluding that the asserted utility is not credible;
- ii) support for factual findings relied upon in reaching this conclusion; and
- iii) support for any conclusions regarding evidence provided by the applicant in support of an asserted utility.

b) Specific evidence that supports any fact-based assertions needed to establish the prima facie showing

Whenever possible, Office personnel must provide documentary evidence (e.g., scientific or technical journals, excerpts from treatises or books, or U.S.

or foreign patents) as the form of support used in establishing the factual basis of a prima facie showing of no utility according to items (a)(ii) and (a)(iii) above. If documentary evidence is not available, Office personnel shall note this fact and specifically explain the scientific basis for the factual conclusions relied on in sections (a)(ii) and (a)(iii).

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered credible by all evidence of record.

Once a prima facie showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR § 1.132 or a printed publication, that rebuts the basis or logic of the prima facie showing. If the applicant responds to the prima facie rejection, Office personnel shall review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a prima facie rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph, per Paragraph (3) above.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of

such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

III. Additional Information

The PTO has prepared an analysis of the law governing the utility requirement to support the guidelines outlined above. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

Date